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PTO/SB/21 (05-03)

Approved for use through 04/30/2003. OMB 0651-0031.

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

**TRANSMITTAL  
FORM**

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

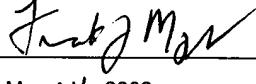
Application Number	10/021,168
Filing Date	December 11, 2001
First Named Inventor	Stephen R. Gorfine
Art Unit	1654
Examiner Name	Christopher Robin Tate

Attorney Docket Number

010692-004531US

ENCLOSURES (Check all that apply)			
<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to Group	
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences	
<input type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)	
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information	
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address	<input type="checkbox"/> Status Letter	
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Terminal Disclaimer	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):	
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Request for Refund	Return Postcard; Copy of IDS's filed 11/14/1997, 08/04/1998, 06/29/1999, 08/25/1999 and 05/14/2001 in parent USN 08/970,447; References AA-AV	
<input checked="" type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> CD, Number of CD(s)		
<input type="checkbox"/> Certified Copy of Priority Document(s)		Remarks	
<input type="checkbox"/> Response to Missing Parts/ Incomplete Application		The Commissioner is authorized to charge any additional fees to Deposit Account 20-1430.	
<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53			

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm or Individual	Townsend and Townsend and Crew LLP Frank J. Mycroft	
Signature		
Date	May 14, 2003	
Reg. No. 46,946		

**CERTIFICATE OF TRANSMISSION/MAILING**

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Typed or printed name	Aaron T. Hokamura		
Signature		Date	May 14, 2003

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Washington, D.C. 20231,  
on

Aug 4, 1998

TOWNSEND and TOWNSEND and CREW LLP

By Anna L. May, Jr.

Attorney Docket No. 10692-045300US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: )  
Stephen R. Gorfine ) Examiner: C. Tate  
Application No.: 08/970,447 ) Art Unit: 1651  
Filed: November 14, 1997 ) INFORMATION DISCLOSURE  
For: NITRIC OXIDE DONOR ) STATEMENT UNDER  
COMPOSITION FOR TREATMENT ) 37 CFR §1.97 and §1.98  
OF ANAL DISORDERS )  
)

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

The references cited on attached form PTO-1449 are being called to the attention of the Examiner. A copy of each is enclosed.

It is respectfully requested that the cited information be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

This IDS is being filed after the mailing date of the first Office Action and after three months of the filing date, but prior to the Notice of Allowance or Final Office Action.

Stephen R. Gorffne  
Application No.: 08/970,447  
Page 2

PATENT

Please charge \$240.00, pursuant to 37 CFR § 1.17p, to Deposit Account No. 20-1430. This Petition is submitted in triplicate.

Please charge any additional fees or credit any overpayment to Deposit Account No. 20-1430.

Respectfully submitted,



Margaret A. Powers  
Reg. No. 39,804

TOWNSEND and TOWNSEND and CREW LLP  
Two Embarcadero Center, 8th Floor  
San Francisco, California 94111-3834  
Telephone (650) 326-2400  
Facsimile (650) 326-2422  
MAP:amc

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**PATENT**  
Attorney Docket No.: 010692-004531US

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

On May 14, 2003

TOWNSEND and TOWNSEND and CREW LLP

By: Aaron Hohmann



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

Stephen R. Gorfine

Application No.: 10/021,168

Filed: December 11, 2001

For: NITRIC OXIDE DONOR  
COMPOSITION AND METHOD FOR  
TREATMENT OF ANAL DISORDERS

Examiner: Christopher Robin Tate

Art Unit: 1654

**INFORMATION DISCLOSURE  
STATEMENT UNDER 37 CFR §1.97 and  
§1.98**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The references cited on attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. Copies of these references are being submitted herewith. Please also find attached a copy of the Information Disclosure Statement filed November 14, 1997, the Information Disclosure Statement filed August 4, 1998, the Supplemental Information Disclosure Statement filed June 29, 1999, the Second Supplemental Information Disclosure Statement filed August 25, 1999 and the Information Disclosure Statement filed May 14, 2001, all of the parent case, U.S. Patent Application No. 08/970,447, filed November 14, 1997 (Attorney Docket No. 10692-004530US). In accordance with 37 CFR §1.98(d), copies of the

references cited on these Information Disclosure Statements are not enclosed. Additional copies of these references will be provided immediately upon the Examiner's request. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Applicant believes that no fee is required for submission of this statement. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,



Frank J. Mycroft  
Reg. No. 46,946

TOWNSEND and TOWNSEND and CREW LLP  
Two Embarcadero Center, 8<sup>th</sup> Floor  
San Francisco, California 94111-3834  
Tel: 925-472-5000  
Fax: 925-472-8895

FJM:ath

WC 9056788 v1

"Express Mail" Label No. 44875335US  
Date of Deposit: June 29, 1999

**PATENT**  
Attorney Docket No.: 10692-004530



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On 6-29-99

TOWNSEND and TOWNSEND and CREW LLP

By: Mr. Myer

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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Stephen R. Gorfine

Application No.: 08/970,447

Original Filing Date of Application:  
November 14, 1997

Filing Date of Continued Prosecution  
Application: Filed Herewith

For: NITRIC OXIDE DONOR  
COMPOSITION FOR TREATMENT OF  
ANAL DISORDERS

Examiner: C. Tate

Art Unit: 1651

SUPPLEMENTAL INFORMATION  
DISCLOSURE STATEMENT UNDER 37  
CFR §1.97 and §1.98

Box CPA  
Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

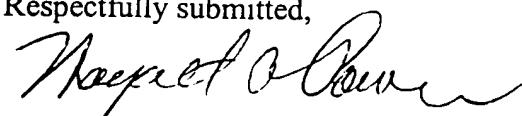
The references cited on attached form PTO-1449 are being called to the attention of the Examiner. Copies of the references are enclosed. It is respectfully requested that the cited information be expressly considered during the prosecution of this application.

and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 C.F.R. §§ 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Applicant believes that no fee is required for submission of this statement, since it is being submitted prior to the first Office Action. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,



Margaret A. Powers  
Reg. No. 39,804

TOWNSEND and TOWNSEND and CREW LLP  
Two Embarcadero Center, 8<sup>th</sup> Floor  
San Francisco, California 94111-3834  
Tel: 650-326-2400  
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

## **INFORMATION DISCLOSURE STATEMENT**

Hon. Commissioner of Patents  
and Trademarks  
Washington, D.C. 20231

Dear Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is requested that this Information Disclosure Statement be entered and the documents listed below and on the enclosed Form PTO-1449 be considered by the Examiner and made of record.

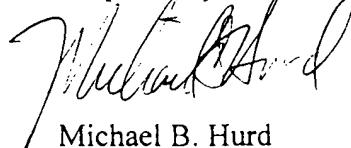
1. U.S. Patent No. 4,118,480 issued October, 1978 to Williams.
2. U.S. Patent No. 5,059,603 issued October, 1991 to Rubin.
3. U.S. Patent No. 4,292,299 issued September, 1981 to Suzuki et al.
4. U.S. Patent No. 2,840,080 issued June, 1958 to Clark.
5. U.S. Patent No. 5,183,663 issued February, 1993 to Greiner.
6. U.S. Patent No. 814,408, issued March, 1906 to Steele.

7. Rattan, et al., "Nitric Oxide Pathway in Rectoanal Inhibitory Reflex of Opossum Internal Anal Sphincter," NO As a Gut Smooth Muscle-Inhibitory Mediator, 1992.
8. Rattan, et al., "Role of Nitric Oxide as a Mediator of Internal Anal Sphincter Relaxation," Nitric Oxide As Gut Smooth Muscle Inhibitory Mediator, pages G107-G112, 1991.
9. O'Kelly, et al., "Nerve Mediated Relaxation of the Human Internal Anal Sphincter: The Role of Nitric Oxide," Gut, pages 689-693, 1993.
10. Chakder, et al., "Release of Nitric Oxide by Activation of Nonadrenergic Noncholinergic Neurons of Internal Anal Sphincter," NO Release By Nanc Neural Stimulation and VIP, pages G7-G12, 1992.
11. Loder, et al., "Reversible Chemical Sphincterotomy by Local Application of Glyceryl Trinitrate," British Journal of Surgery, pages 1386-1389, 1994.
12. Shafik, "Role of Warm-Water Bath in Anorectal Conditions: The Thermosphincteric Reflex," J. Clin. Gastroenterol., 16:304-308, 1993.
13. Gillespie et al., "Influence of Haemoglobin and Erythrocytes on the Effects of EDRF, a Smooth Muscle Inhibitory Factor, and Nitric Oxide on Vascular and Non-Vascular Smooth Muscle," Br. J. Pharmacol., 95:1151-1156, 1988.
14. Ignarro et al., "Nitric Oxide and Cyclic GMP Formation Upon Electrical Field Stimulation Cause Relaxation of Corpus Cavernosum Smooth Muscle," Biochem. Biophys. Res. Commun., 170:843-850, 1990.
15. Bult et al., "Nitric Oxide as an Inhibitory Non-Adrenergic Non-Cholinergic Neurotransmitter," Nature, 345:346-347, 1990.

16. Feelisch et al., "Correlation Between Nitric Oxide Formation During Degradation of Organic Nitrates and Activation of Guanylate Cyclase," Eur. J. Pharmacol., 139:19-30, 1987.
17. Fung et al., "Biochemical Mechanism of Organic Nitrate Action," Am. J. Cardiol., 70:4B-10B, 1992.
18. Huff et al. (Eds.), "Physicians' Desk Reference," 41st Edition, Medical Economics Company, Oradell, N.J., 1987, at pages 780, 1176-78, 1533 and 1984-85.
19. Budavari et al. (Eds.), "The Merck Index," 11th Edition, Merck & Co., Rahway, N.J., 1989, pp. 198 and 821 (isopropyl nitrate).
20. Loder et al. "AGA Abstracts" Gastroenteroloy, Vol. 104, No. 4, 1993.
21. Guillemot, et al., "Action of In Situ Nitroglycerin on Upper Anal Canal Pressure of Patients with Terminal Constipation" Dis Colon Rectum, April 1993.

A copy of the references listed above were cited in application Serial No. 08/666,264, filed June 20, 1996, which was a continuation of application Serial No. 08/371,088, filed January 10, 1995, which was a continuation-in-part application of U.S. Patent No. 5,504,117 which issued April 2, 1996. Copies of those references can be obtained from the referenced applications.

Respectfully submitted,



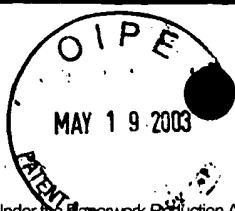
Michael B. Hurd  
Reg. No. 32,241

MBH/tjd

November 14, 1997

Michael B. Hurd  
SHOOK, HARDY & BACON L.L.P.  
One Kansas City Place  
1200 Main Street  
Kansas City, Missouri 64105-2118  
(816) 474-6550 (Ext. 30083)

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Page 1 of 2

### Complete if Known

Application Number	10/021,168
Filing Date	December 11, 2001
First Named Inventor	Stephen R. Gorfine
Art Unit	1654
Examiner Name	Christopher Robin Tate
Attorney Docket Number	010692-004531US

### U.S. PATENT DOCUMENTS

Examiner	Cite No. <sup>1</sup>	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	AA	US-4,226,849		10/07/1980	Schor	
	AB	US-4,371,516		02/01/1983	Gregory et al.	
	AC	US-4,514,384		04/30/1985	Gallina	
	AD	US-4,608,249		08/26/1986	Otsuka et al.	
	AE	US-4,654,209		03/31/1987	Leslie et al.	
	AF	US-4,657,906		04/14/1987	Emmet et al.	
	AG	US-4,683,242		07/28/1987	Poser	
	AH	US-4,746,675		05/24/1988	Makino et al.	
	AI	US-4,842,854		06/27/1989	Babaian et al.	
	AJ	US-5,047,230		09/10/1991	Nagy et al.	
	AK	US-5,059,603		10/22/1991	Rubin	
	AL	US-5,085,650		02/04/1992	Giglio	
	AM	US-5,439,938		08/08/1995	Snyder et al.	
	AN	US-5,508,045		04/16/1996	Harrison et al.	
	AO	US-5,595,970		01/21/1997	Garfield et al.	

### FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
✓	AP	DE	304,730		03/01/1989	Dunzendorfer et al.		<input type="checkbox"/>
✓	AQ	DE	4,038,203 (abstract)		06/04/1992	Bonnacker et al. (w/ English translation)		<input type="checkbox"/>
✓	AR	JP	62-67017		03/26/1987	Sawai et al. (w/ English translation abstract)		<input type="checkbox"/>

Examiner Signature

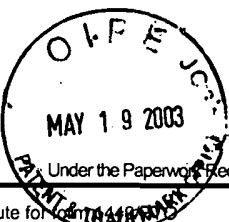
Date Considered

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<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Kind Codes of U.S. Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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of

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### Complete if Known

Application Number	10/021,168
Filing Date	December 11, 2001
First Named Inventor	Stephen R. Gorfine
Art Unit	1654
Examiner Name	Christopher Robin Tate

Attorney Docket Number

010692-004531US

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
✓	AS	Enck <i>et al.</i> , 1991, "Spontaneous variation of anal 'resting' pressure in healthy humans," <i>Am. J. Physiol.</i> 261(5 Pt 1):G823-G826	
✓	AT	Farouk <i>et al.</i> , 1994, "Sustained Internal Sphincter Hypertonia in Patients with Chronic Anal Fissure," <i>Dis. Colon Rectum</i> 37:424-429	
✓	AU	Gorfine, SR., 1995, "Treatment of benign anal disease with topical nitroglycerin," <i>Dis. Colon. Rectum</i> 38(5):453-456	
✓	AV	Guillermot <i>et al.</i> , 1993, "Action of <i>in situ</i> nitroglycerin on upper anal canal pressure of patients with terminal constipation. A pilot study." <i>Dis. Colon Rectum</i> 36(4):372-376	

Examiner Signature		Date Considered
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.  
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**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

MAY 20 2003  
TECH CENTER 1600/2900

FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)			Attorney Docket No.: 10692-004530 Applicant: Stephen R. Gorfine Original Filing Date: November 14, 1997 Continued Prosecution Application: Filed Herewith	Application No.: 08/970,447 Group: 1651		
Reference Designation		U.S. PATENT DOCUMENTS			Page 1	
Examiner Initial	Document No.	Date	Name	Class	Sub-class	Filing Date (If Appropriate)
AA ✓	3,419,571	12/31/68	Di Carlo et al.			
FOREIGN PATENT DOCUMENTS						
	Document No.	Date	Country	Class	Sub-class	Translation (Yes/No)
AB ✓	JP2-207880	03/24/92	Japan			Yes
AC ✓	77/1135	2/25/77	South Africa			Yes
AD ✓	625830	7/02/91	Australia			
OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)						
AE ✓	Ahlner et al., "Organic Nitrate Esters: Clinical Use and Mechanisms of Actions," <u>Pharmacol. Reviews</u> 43(3):351-353 (1991).					
AF ✓	Gibbons et al., "Anal hypertonia in fissures; cause or effect?," <u>Br. J. Surgery</u> 73:443-445 (June 1986).					
AG ✓	Loder et al., "Topical Application of a Nitric Oxide Donor Reduces Internal Anal Sphincter Tone: Therapeutic Implications," <u>Abstract, Gut</u> 34: S25, April (1993) T96.					
AH ✓	"External Preparation for Anus," Abstract for Japanese Patent Application No. 02-207880, Japanese Laid-Open Publication No. 04-091036, Inventor Hashioka Tatsuya, JP Nihon Kuringeeji, Japan, Patent Application No. 02-207880 published on March 24, 1992.					
AI ✓	Kennedy et al., "Chemical Sphincterotomy for Anal Fissure - A New Treatment," Abstract, No. CR33, Scientific Programme, Meeting of Royal Australasian College of Surgeons, A.S.C. Hobart, May 1-6, 1994.					
EXAMINER		DATE CONSIDERED				

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



FORM PTO-1449 (Modified)

Attorney Docket No.  
10692-045300USSerial No.:  
08/970,447LIST OF PATENTS AND PUBLICATIONS FOR  
APPLICANT'S INFORMATION DISCLOSURE  
STATEMENT  
(Use several sheets if necessary)P E  
MAY 19 2003  
Applicant: Stephen R. Gorfine

Filing Date: 11/14/97

Group: 1651

## Reference Designation

## U.S. PATENT DOCUMENTS

Examiner Initial	Document No.	Date	Name	Class	Sub-class	Filing Date (If Appropriate)
AA						
AB						
AC						
AD						
AE						
AF						

## FOREIGN PATENT DOCUMENTS

	Document No.	Date	Country	Class	Sub-class	Translation (yes/no)
AM						
AN						
AO						
AP	7,701,135	04/12/78	South Africa			Y
AQ	WO 95/06466	03/09/95	PCT			Y

## OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

AR	Schouten et al., "Pathophysiological Aspects and Clinical Outcome of Intra-anal Application of Isosorbide-di-Nitrate in Patients with Chronic anal Fissure," <u>Dis Colon Rectum</u> , Podium Presentations, April 1995, P18 (50).
AS	Loder et al., "Topical Application of a Nitric Oxide Donor Reduces Internal Anal Sphincter Tone: Therapeutic Implications," Abstract, <u>Gut</u> 1993 34 S25, April, (1993) T96.
AT	Loder et al., "Topical Glyceryl Trinitrate (GTN): Reversible Chemical Sphincterotomy," American Society of Colon and Rectal Surgeons 92nd Annual Convention Podium and Poster Abstracts, Chicago, IL (May 2-7, 1993), <u>Dis Colon Rectum Meeting Abstracts</u> , April 1993, P22 (64).
AU	S. Jensen, "Treatment of First Episodes of Acute Anal Fissure: Prospective Randomised Study of Lignocaine Ointment Versus Hydrocortisone Ointment or Warm Sitz Baths Plus Bran," 1986.
AV	Rattan et al., "Nitric Oxide Pathway in Rectoanal Inhibitory Reflex of Oppossum Internal Anal Sphincter," <u>Gastroenterology</u> 103:43-50 (1992).
AX	Watson et al., "Glyceryl Trinitrate and Anal Fissure: Resistance to Endogenous Nitric Oxide and Tachyphylaxis," <u>Diseases of the Colon &amp; Rectum</u> 38(4), April 1995, P29.

EXAMINER

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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



2 Sheets

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE  INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Attorney Docket No.	Serial Number
	GRFS.54767	
	Applicant Stephen R. Gorfine	
Filing Date	Group	

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE
	4,118,480	10/78	Williams			
	5,059,603	10/91	Rubin			
	4,292,299	9/81	Suzuki et al.			
	2,840,080	6/58	Clark			
	5,183,663	2/93	Greiner			
	814,408	3/06	Steele			

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

EXAMINER INITIAL	DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUBCLASS	TRANSLATION	
						YES	NO

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

	Rattan, et al., "Nitric Oxide Pathway in Rectoanal Inhibitory Reflex of Opossum Internal Anal Sphincter", <u>No As a Gut Smooth Muscle-Inhibitory Mediator</u> , 1992.
	Rattan, et al., "Role of Nitric Oxide as a Mediator of Internal Anal Sphincter Relaxation", <u>Nitric Oxide As Gut Smooth Muscle Inhibitory Mediator</u> , pages G107-G112, 1991.
	O'Kelly, et al., "Nerve Mediated Relaxation of the Human Internal Anal Sphincter: The Role of Nitric Oxide", <u>Gut</u> , pages 689-693, 1993.
	Chakder, et al., "Release of Nitric Oxide by Activation of Nonadrenergic Noncholinergic Neurons of Internal Anal Sphincter", <u>No Release By Nanc Neural Stimulation and VIP</u> , pages G7-G12, 1992.
	Loder, et al., "Reversible Chemical Sphincterotomy by Local Application of Glyceryl Trinitrate", <u>British Journal of Surgery</u> , pages 1386-1389, 1994.
	Shafik, "Role of warm-water bath in anorectal conditions: The 'thermosphincteric reflex,'" <u>J. Clin. Gastroenterol.</u> , 16:304-308, 1993.

	Gillespie et al., "Influence of haemoglobin and erythrocytes on the effects of EDRF, a smooth muscle inhibitory factor, and nitric oxide on vascular and non-vascular smooth muscle," <u>Br. J. Pharmacol.</u> , 95:1151-1156, 1988.
	Ignarro et al., "Nitric oxide and cyclic GMP formation upon electrical field stimulation cause relaxation of corpus cavernosum smooth muscle," <u>Biochem. Biophys. Res. Commun.</u> , 170:843-850, 1990.
	Bult et al., "Nitric oxide as an inhibitory non-adrenergic non-cholinergic neurotransmitter," <u>Nature</u> , 345:346-347, 1990.
	Feelisch et al., "Correlation between nitric oxide formation during degradation of organic nitrates and activation of guanylate cyclase," <u>Eur. J. Pharmacol.</u> , 139:19-30, 1987.
	Fung et al., "Biochemical mechanism of organic nitrate action," <u>Am. J. Cardiol.</u> , 70:4B-10B, 1992.
	Huff et al. (Eds.), "Physicians' Desk Reference," 41st Edition, Medical Economics Company, Oradell, N.J., 1987, at pages 780, 1176-78, 1533 and 1984-85.
	Budavari et al. (Eds.), "The Merck Index," 11th Edition, Merck & Co., Rahway, N.J., 1989, pp. 198 and 821 (isopropyl nitrate).
	Loder et al. "AGA Abstracts" <u>Gastroenterology</u> , Vol. 104, No. 4, 1993.
	Guillemot, et al., "Action of In Situ Nitroglycerin on Upper Anal Canal Pressure of Patients with Terminal Constipation" <u>Dis Colon Rectum</u> , April 1993.

EXAMINER	DATE CONSIDERED
EXAMINER: Initial citation if reference was considered. Draw line through citation if not in conformance to MPEP 609 and not considered. Include copy of this form with next communication to applicant.	



FORM PTO-1449 (Modified)		Attorney Docket No.: 10692-004571US	Application No.: 09/286,251
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant: Stephen R. Gorfine	
		Filing Date: April 5, 1999	Group: 1651

Reference Designation		U.S. PATENT DOCUMENTS			Page 1	
Examiner Initial	Document No.	Date	Name	Class	Sub-class	Filing Date (If Appropriate)
AA ✓	5,504,117 ✓	April 2, 1996	Steven R. Gorfine (Exhibit PBL-20 to Loder Dec. of Oct. 11, 2000.)	514	742	May 27, 1994

#### FOREIGN PATENT DOCUMENTS

	Document No.	Date	Country	Class	Sub-class	Translation (Yes/No)
AB ✓	WO 98/36733	27 Aug. 1998	PCT (Exhibit DZL-8 to Lubowski Dec., (Oct. 16, 2000)	A61K	9/06	No
AC ✓	74545/94	Filed 19 Aug. 1994	Australian Patent Application (Exhibit PBL-1 to Statutory Declaration of Loder of Oct. 11, 2000)			No.
AD ✓	PM 0971	3/22/95	Australian Provisional Patent Application (Exhibit PBL-1 to Statutory Declaration of Loder of Oct. 11, 2000)			No.
AE ✓	PM 4247	3/22/95	Australian Provisional Patent Application (Exhibit PBL-1 to Statutory Declaration of Loder of Oct. 11, 2000)			No.
AF ✓	PM 6395	7/14/94	Australian Provisional Patent Application (Exhibit PBL-1 to Statutory Declaration of Loder of Oct. 11, 2000)			No.

#### OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

AG ✓	Statutory Declaration of David Z. Lubowski in Australian Patent application Number 708694 in the name of Cellegy Australia Pty. Ltd. in the matter of Opposition thereto by Peter Bruce Loder (October 16, 2000).
AH ✓	Curriculum Vitae of Lubowski, Exhibit DZL-1 to Statutory Declaration of Lubowski (October 16, 2000).
AI ✓	Lubowski, D. et al., "Neural control of internal anal sphincter function," Br. J. Surg. 74: 668-670 (August 1987), Exhibit DZL-2 to Statutory Declaration of Lubowski (October 16, 2000).
AJ ✓	Burleigh, D. and D'Mello, A., "Physiology and Pharmacology of the Internal Anal Sphincter", Chapter 2, pages 22-41 (1985), in <i>Coloproctology and The Pelvic Floor</i> , Henry and Swash, eds., Butterworth Publishers, Stoneham, Mass., USA and London, England, ISBN 0-407-00352-5. 0 (0), Exhibit DZL-3 to Statutory Declaration of Lubowski (October 16, 2000).
AK ✓	Burleigh, D., "Ng-Nitro-L-Arginine Reduces Nonadrenergic Relaxations of Human Gut," <i>Gastroenterology</i> , 102: 679-683 (1992), Exhibit DZL-4 to Statutory Declaration of Lubowski (October 16, 2000).
AL ✓	Rattan, S. and Chakder, S., "Role of nitric oxide as a mediator of internal anal sphincter relaxation," <i>Am. J. Physiol.</i> G107-G112 (1992), Exhibit DZL-5 to Statutory Declaration of Lubowski (October 16, 2000).
AM ✓	Rattan, S. et al., "Nitric Oxide Pathway in Rectoanal Inhibitory Reflex of Opossum Internal Anal Sphincter," <i>Gastroenterology</i> 103: 43-50 (1992), Exhibit DZL-6 to Statutory Declaration of Lubowski (October 16, 2000).
AN ✓	Tottrup, A. et al., "Involvement of the L'Arginine-Nitric Oxide Pathway in Internal Anal Sphincter Relaxation," <i>Gastroenterology</i> 102: 409-41 (1992), Exhibit DZL-7 to Lubowski Declaration (October 16, 2000).





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FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Attorney Docket No.: 10692-004571US	Application No.: 09/286,251
		Applicant: Stephen R. Gorfine	
		Filing Date: April 5, 1999	Group: 1651
AO	✓ Phillips, R, letter to Lubowski re confirmation re appointment to Royal Society of Medicine as Visiting Professor and Frederick Salmon Lecturer (October 29, 1998); letter to Lubowski re itinerary as Visiting Professor and Frederick Salmon Lecturer (May 12, 1998); announcement of Lubowski lecture at St. Mark's Academic Institute, December 10, 1998), all Exhibit DZL-9 to Lubowski Statutory Declaration (October 16, 2000).		
AP	✓ Loder, P. et al, "Topical Glyceryl Trinitrate (GTN): Reversible Chemical Sphincterotomy," Meeting Abstracts, Dis Colon Rectum P22 (April 1993), Exhibit DZL-10 to Statutory Declaration of Lubowski (October 16, 2000).		
AQ	✓ Loder, P. et al., "Topical Application of a Nitric Oxide Donor Reduces Internal Anal Sphincter Tone: Therapeutic Implications," AGA Abstracts, <i>Gastroenterology</i> , 104: A544 (April 1993), Exhibit DZL-11 to Statutory Declaration of Lubowski (October 16, 2000).		
AR	✓ Loder, P. et al, "Topical Application of a Nitric Oxide Donor Reduces Internal Anal Sphincter Tone: Therapeutic Implications," <i>Gut</i> 34: S25 (March 1993), Exhibit DZL-12 to Statutory Declaration of Lubowski (October 16, 2000).		
AS	✓ Loder, P. et al., "'Reversible Chemical Sphincterotomy' by local application of glyceryl trinitrate," <i>British Journal of Surgery</i> 81: 1386-1389 (1994), Exhibit DZL-13 to Statutory Declaration of Lubowski (October 16, 2000).		
AT	✓ Lubowski, D., letter to Loder re topical GTN work (July 25, 1998), Exhibit DZL-14 to Statutory Declaration of Lubowski (October 16, 2000).		
AU	✓ Statutory Declaration of Michael L. Kennedy in the matter of Australian Patent/ Application Number 708694 in the name of Cellegy Australia Pty. Ltd. (October 12, 2000).		
AV	✓ Statutory Declaration of Simon Brookes in the matter of Australian Patent/Application Number 708694 in the name of Cellegy Australia Pty. Ltd. (October 11, 2000).		
AW	✓ Statutory Declaration of Carol Marchei in the matter of Australian Patent/Application Number 708694 in the name of Cellegy Australia Pty. Ltd. (October 11, 2000).		
AX	✓ Statutory Declaration of Lawrence G. Howes in the matter of Australian Patent/Application Number 708694 in the name of Cellegy Australia Pty. Ltd. (October 12, 2000).		
AY	✓ <i>Curriculum Vitae</i> of Lawrence G. Howes, Exhibit LGH-1 to Statutory Declaration of Lawrence G. Howes (October 12, 2000).		
AZ	✓ Statutory Declaration of Peter Bruce Loder in the matter of Australian Patent Application No. 708694 in the name of Koren Laboratories Pty. Ltd. (October 11, 2000).		
BA	✓ <i>Curriculum Vitae</i> of Peter Bruce Loder, Exhibit PBL-2 to Statutory Declaration of Peter Bruce Loder (October 11, 2000).		
BB	✓ Keighley, R. and Williams, N. "Anatomy and Physiology," Chapter One, <i>Surgery of the Anus, Rectum and Colon</i> , London, W.B. Saunders (1993), Exhibit PBL-3 to Statutory Declaration of Peter Bruce Loder (October 11, 2000).		
BC	✓ Keighley, R. and Williams, N., "Anatomy and Physiology," Chapter One, <i>Surgery of the Anus, Rectum and Colon</i> , page 5, Exhibit PBL-4 to Statutory Declaration of Peter Bruce Loder (October 11, 2000).		
BD	✓ Lord, P., "A Day-Case Procedure for the Cure of Third-Degree Haemorrhoids," <i>British Journal of Surgery</i> 56(10): 747-9 (1969), part of Exhibit PBL-5 to Statutory Declaration of Peter Bruce Loder (October 11, 2000).		
BE	✓ Jalan, K. et al., "Perineal Wound Healing in Ulcerative Colitis," <i>British Journal of Surgery</i> (October 1969) 56(10):749-53, part of Exhibit PBL-5 to Statutory Declaration of Peter Bruce Loder (October 11, 2000).		
BF	✓ MacDonald, A. et al., "Manual dilation of the anus," <i>British Journal of Surgery</i> 79:1381-1382 (December 1992), part of Exhibit PBL-5 to Statutory Declaration of Peter Bruce Loder (October 11, 2000).		
BG	✓ Speakman, C. et al., "Sphincter injury after anal dilation demonstrated by anal endosonography," <i>British Journal of Surgery</i> 78: 1429-1430 (December 1991), part of Exhibit PBL-5 to Statutory Declaration of Peter Bruce Loder (October 11, 2000).		
BH	✓ O'Kelley, T. et al, "Nerve mediated relaxation of the human internal anal sphincter: the role of nitric oxide," <i>Gut</i> 34: 689-693 (1993), Exhibit PBL-6 to Statutory Declaration of Peter Bruce Loder (October 11, 2000).		
BI	✓ Mims Annual, Fifteenth Edition, 2-75 (1991), Exhibit PBL-7 to Statutory Declaration of Peter Bruce Loder (October 11, 2000), p. 2042.		
BJ	✓ Loder, P., letter to Dr. D. Scott of St. Mark's Hospital, attaching an Application for Ethical Approval (February 27, 1992), Exhibit PBL-8 to Statutory Declaration of Peter Bruce Loder (October 11, 2000).		
BK	✓ List of Registrants at 92nd Annual Convention of May 2-7, 1993 at Chicago, Illinois of the American Society of Colon and Rectal Surgeons, Exhibit PBL-9 to Statutory Declaration of Peter Bruce Loder (October 11, 2000).		

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		Applicant: Stephen R. Gorfine	
		Filing Date: April 5, 1999	Group: 1651
BL	✓	Program of the Annual Meeting of The American Gastroenterological Associate and Digestive Disease Week, May 15-21, 1993 at Boston, Massachusetts, part of Exhibit PBL-10 to Statutory Declaration of Peter Bruce Loder (October 11, 2000).	
BM	✓	Loder, P. <i>et al.</i> , "Topical Application of a Nitric Oxide Donor Reduces Internal Anal Sphincter Tone: Therapeutic Implications," AGA Abstracts, <i>Gastroenterology</i> , 104: A544 (April 1993), part of Exhibit PBL-10 to Statutory Declaration of Peter Bruce Loder (October 11, 2000).	
BN	✓	Loder, P. <i>et al.</i> , "Topical Application of a Nitric Oxide Donor Reduces Internal Anal Sphincter Tone: Therapeutic Implications," <i>Gas</i> 34: S25 (March 1993), Exhibit DZL-12 to Statutory Declaration of Lubowski (October 16, 2000). part of Exhibit PBL-10 to Statutory Declaration of Peter Bruce Loder (October 11, 2000).	
BO	✓	Loder, P. <i>et al.</i> , "Topical Glyceryl Trinitrate (GTN): Reversible Chemical Sphincterotomy," Meeting Abstracts, <i>Dis. Colon Rectum</i> 22 (April 1993), part of Exhibit PBL-10 to Statutory Declaration of Peter Bruce Loder (October 11, 2000).	
BP	✓	Extract of Proceedings of the Royal Australasian College of Surgeons and Australian and New Zealand College of Anaesthetists Annual Scientific Congress, Adelaide, May 10-14, 1993, including listing of lectures, including Loder, P. <i>et al.</i> , "Reversible Chemical Sphincterotomy by Topical Application of Glyceryl Trinitrate (GTN). (CR15	
BQ	✓	Copies of slides used by Peter Bruce Loder at Manchester (March 1993), Chicago (May 1993), Boston (May 1993) and Adelaide (May 1993) conferences, Exhibit PBL-12 to Statutory Declaration of Peter Bruce Loder (October 11, 2000).	
BR	✓	Loder, P. <i>et al.</i> , "Reversible chemical sphincterotomy" by local application of glyceryl trinitrate, <i>British Journal of Surgery</i> 81: 1386-1389 (1994), Exhibit PBL-13 to Statutory Declaration of Peter Bruce Loder (October 11, 2000).	
BS	✓	Extract of St. Mark's Hospital Year Book Report pages 40-41 (1992), Exhibit PBL-14 to Statutory Declaration of Peter Bruce Loder (October 11, 2000).	
BT	✓	Lund, J. <i>et al.</i> , "Use of glyceryl trinitrate ointment in the treatment of anal fissure," <i>British Journal of Surgery</i> 83: 776-777 (1996), part of Exhibit PBL-15 to Statutory Declaration of Peter Bruce Loder (October 11, 2000).	
BU	✓	Lund, J. and Scholefield, J., "A randomised, prospective, double-blind, placebo-controlled trial of glyceryl trinitrate ointment in treatment of anal fissure," <i>Lancet</i> , 349: 11-14 (January 4, 1997), part of PBL-15 to Statutory Declaration of Peter Bruce Loder (October 11, 2000).	
BV	✓	Copies of eight slides produced to the Australian Patent Office as documents presented at the Sydney Colorectal Surgical Society at St. George Hospital (July 17, 1993), Exhibit PBL-16 to Statutory Declaration of Peter Bruce Loder (October 11, 2000).	
BW	✓	Kennedy, M. <i>et al.</i> , "Glyceryl Trinitrate Ointment for the Treatment of Chronic Anal Fissure," <i>Dis Colon Rectum</i> 42(8): 1000-1006 (August 1999), Exhibit PBL-17 to Statutory Declaration of Peter Bruce Loder (October 11, 2000).	
BX	✓	Kennedy, M. <i>et al.</i> , "Chemical Sphincterotomy for Anal Fissure - A New Treatment," Abstract CR33, presentation at Royal Australasian College of Surgeons at Hobart, Tasmania meeting of May 1-6, 1994.	
BY	✓	E-mail of J. Scholefield to P. Loder re Dr. Gorfine (April 1, 1997), part of Exhibit PBL-19 to Statutory Declaration of Peter Bruce Loder (October 11, 2000).	
BZ	✓	E-mail of J. Scholefield to P. Loder re Dr. Gorfine (July 24, 1997), part of Exhibit PBL-19 to Statutory Declaration of Peter Bruce Loder (October 11, 2000).	
CA	✓	E-mail of P. Stein to P. Loder re GTN product (August 8, 1997), part of Exhibit PBL-19 to Statutory Declaration of Peter Bruce Loder (October 11, 2000).	
CB	✓	Letter of P. Loder to D. Lubowski re treatment of fissures (July 18, 2000), Exhibit PBL-22 to Statutory Declaration of Peter Bruce Loder (October 11, 2000).	
CC	✓	E-mail from J. Scholefield to P. Loder re GTN and D. Lubowski (August 1, 1998), Exhibit PBL-23 to Statutory Declaration of Peter Bruce Loder (October 11, 2000).	
CD	✓	Letter from P. Stein of Norgine to P. Loder re Drs. Gorfine and Lubowski (September 18, 2000), Exhibit PBL-24 to Statutory Declaration of Peter Bruce Loder (October 11, 2000).	
CE	✓	Notes by P. Loder of telephone conversations with D. Lubowski of November 24 and 28, 1999, Exhibit PBL-25 to Statutory Declaration of Peter Bruce Loder (October 11, 2000).	

EXAMINER

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